

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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IN RE PHARMACEUTICAL INDUSTRY } MDL No. 1456  
AVERAGE WHOLESALE PRICE } CIVIL ACTION: 01-CV-12257-PBS  
LITIGATION } Judge Patti B. Saris

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THIS DOCUMENT RELATES TO }  
01-CV-12257-PBS AND 01-CV-339 }

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**OPPOSITION TO BOEHRINGER INGELHEIM CORPORATION,  
BEN VENUE LABORATORIES, INC. AND BEDFORD LABORATORIES'  
MOTION FOR A PROTECTIVE ORDER**

The Boehringer Defendants' Motion for a Protective Order should swiftly be denied. Boehringer, along with all other defendants moved against the AMCC and filed two defendant specific briefs. The Court denied Boehringer's motion on February 24, 2004.

On March 25, 2004, the Court entered CMO No. 10 requiring Boehringer to respond to discovery. Thereafter, on April 7, 2004, Boehringer filed a motion to dismiss raising yet new grounds for dismissal, grounds it could and should have asserted previously. Based on its latest dismissal motion Boehringer now seeks a stay. This latest dismissal motion asserts that the only Boehringer drug for which a purchaser is identified in the AMCC is Atrovent, which Boehringer claims it does not manufacture, hence it seeks dismissal.

This stay motion suffers from three flaws.

First, Atrovent was identified as a Boehringer drug in the AMCC at the time of the dismissal motions which formed the basis of the Court's February 24, 2004 Order. If Boehringer believed it did not manufacture this drug, and hence there was a lack of standing, it should have been raised then and this issue could have been readily addressed. To justify the untimeliness of its motion Boehringer claims that the "December 5 AMCC indicated, *for the first time*, that Plaintiffs claimed standing to sue due to the purchase of Atrovent." Boehringer Memorandum in Support of Motion for a Protective Order at p. 3 (emphasis in memorandum). Yet in the version of the Complaint prior to the corrected AMCC, plaintiff New York Statewide Senior Action Council ("Statewide") identified a member who purchased Atrovent. (AMCC ¶ 34.) Thus, Boehringer was plainly on notice that Atrovent was at issue and failed to raise its "we did not manufacture" Atrovent argument. And, Boehringer could have raised this issue in response to the notice of filing of the modified AMCC, but did not. Instead, it waited until after it lost the motion to dismiss. Its latest motion is untimely.

Second, any plaintiff standing issues as to the drugs it does not now disavow manufacturing are cured by the proposed addition of the Sprinkler Fund ("Sprinkler") as a named

plaintiff.<sup>1</sup> Sprinkler purchased drugs manufactured by Bedford Laboratories, a division of Ben Venue, which is part of the Boehringer Group. And to the extent Boehringer is now claiming for the first time that plaintiffs have named the wrong party, plaintiffs have moved to cure that new issue as well.<sup>2</sup>

Third, as the Court made clear in CMO No. 11; CMO No. 10 applies to the government actions as well. In the Montana and Nevada actions the states each allege, in their *parens patriae* capacity, that citizens of each state purchased drugs manufactured by the Boehringer defendants. *See* Montana Complaint ¶¶ 2, 19-20, 30, 644-49, 653, 655. Appendix A to the Montana Complaint and ¶ 343 of the Complaint identify dozens of Boehringer drugs at issue and specifies AWP inflation on these drugs often as high as 1000% or more. Boehringer is subject to discovery in the states' cases and the standing issue is not bar to discovery in those cases hence there is no basis for a stay.

Finally, to the extent Boehringer *now* on its third dismissal motion submits affidavits they should be disregarded as they are procedurally improper and highly suspect. For example, Boehringer submits the affidavit of Herman Tetzner who claims that "BIC does not design, manufacture or distribute[] Atrovent or any other pharmaceutical products." However, Boehringer Ingelheim's website contradicts this affidavit, to put it mildly. First, the website describes the company as follows: "Our business consists of Prescription medicines."<sup>3</sup> This of course contradicts Tetzner's affidavit which states that Boehringer is not in the pharmaceutical product business. The website then notes that "Boehringer Ingelheim's product range is mainly focused on human pharmaceuticals...."<sup>4</sup> Again a contradiction of Tetzner's affidavit. And later, the website identifies Atrovent as a drug manufactured by Boehringer.<sup>5</sup> At best, being charitable

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<sup>1</sup> *See* National Automatic Sprinkler Industry Welfare Funds Motion to Intervene filed on April 27, 2004.

<sup>2</sup> *See* Motion to Substitute Proper Party filed on April 27, 2004.

<sup>3</sup> *See* Exhibit A attached hereto.

<sup>4</sup> Attached as Exhibit B.

<sup>5</sup> Attached as Exhibit C.

to the Tetzner affidavit, it cannot at this stage provide a basis for a stay on the grounds that the Boehringer Group does not manufacture Atrovent, a drug for which the Boehringer Group otherwise admits standing exists by virtue of a plaintiff having purchased this drug and the inconsistency between the affidavit and the website highlights the need for discovery

The Court has provided defendants with multiple filings against the AMCC. It has set a schedule for the Phase 2 discovery and the Boehringer Group is and should be subject to that schedule. The motion for a stay should be denied.

DATED: April 29, 2004

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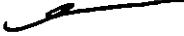
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**CERTIFICATE OF SERVICE**

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing OPPOSITION TO BOEHRINGER INGELHEIM CORPORATION, BEN VENUE LABORATORIES, INC. AND BEDORD LABORATORIES' MOTION FOR A PROTECTIVE ORDER to be served on all counsel of record electronically on April 29, 2004, pursuant to Section D of Case Management Order No. 2.

  
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## **EXHIBIT A**



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## Prescription Medicines

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### Boehringer Ingelheim human pharmaceuticals: effective primary and specialist care worldwide

Boehringer Ingelheim's product range is mainly focused on human pharmaceuticals, which contribute the largest share of the turnover of the [Boehringer Ingelheim group of companies](#), accounting for 96% of [net sales in 2003](#).

Human pharmaceuticals business covers the areas:

- [Prescription Medicines](#) - these need prescription either by general practitioners for primary care or by specialists in certain indications or these are products, which form an integral part of hospital treatment.
- [Consumer Health Care](#) - comprises products which need no prescription and are chosen by the users themselves.
- Activities grouped under Industrial Customer include [Chemicals](#) and [Biopharmaceuticals](#).

In prescription medicines, Boehringer Ingelheim has built on its traditional areas of expertise:

- [Cardiovascular diseases](#):  
[Acute Coronary Disease](#), [Hypertension](#)
- [Diseases of the Central Nervous System](#):  
[Parkinson Disease](#), [Stroke](#)
- [Respiratory Diseases](#):  
[Chronic Obstructive Pulmonary Disease](#) [COPD](#)

In recent years, we have also focused on new indication areas such as:

- [HIV/AIDS](#)
- [Arthritis](#)
- [Benign Prostatic Hyperplasia](#) and other urological disorders

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# Products

## Innovation in Business

Boehringer Ingelheim is a research-driven group of companies dedicated to researching, developing, manufacturing and marketing pharmaceuticals that improve health and quality of life.

Our business consists of Prescription Medicines, Consumer Health Care and Animal Health. Activities grouped under Industrial Customer include Biopharmaceuticals and Chemicals.

We focus on the production of innovative drugs and treatments that represent major therapeutic advances.

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## **EXHIBIT C**



## Chronic Obstructive Pulmonary Disease COPD

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**Chronic Obstructive Pulmonary Disease COPD is a major health and socio-economic burden; one of the top five causes of disability and death in industrial societies.**

COPD is a chronic respiratory disorder characterised by airflow limitation, accompanied by shortness of breath, cough, wheezing and increased sputum production. Patients are unable to perform their usual daily activities. COPD is mainly associated with smoking, with up to 20% of all smokers developing the disease. COPD progresses with age, leading to disability and early death.

According to the Annual World Health Report of the World Health Organisation (WHO), about 600 million people suffer from COPD, with some three million dying from the disease each year.

COPD comprises chronic obstructive bronchitis and emphysema.

COPD and asthma can co-exist. However, COPD is different from asthma in many ways. COPD is mostly associated with a long smoking history; asthma is mostly associated with allergy and occurs early in life. COPD lung function abnormalities develop before symptoms are reported by the patient, typically around the age of 45. On a histo-pathological level, a different type of inflammatory mechanism is involved.

For years, COPD received less attention than asthma from the medical profession, being generally perceived as a self-inflicted irreversible disease. A number of national and international guidelines have been created to improve the diagnosis of COPD and provide guidance on the optimal management of stable and acute phases of the disease.

Anticholinergics, a traditional core competence of Boehringer Ingelheim, are the first line recommendation for the management of COPD in many guidelines. Their qualities beyond bronchodilatation, i.e. improvement of dyspnoea, exercise tolerance, promoting sleep quality, decreasing COPD exacerbations and improving disease related quality of life for patients is the focus of ongoing modern clinical research. These improvements were to some extent already seen with marketed anticholinergics, but have become significantly greater with new developments.

The most effective intervention in COPD remains giving up smoking. Consequently smoking cessation should be standard treatment for COPD, accompanied by the usage of bronchodilators.

Spiriva® (tiotropium)

Indicated as a bronchodilator for the maintenance treatment of chronic obstructive pulmonary disease (COPD).

**Atrovent® (ipratropium bromide)**

Indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis, emphysema and asthma.

**Combivent® (ipratropium bromide/salbutamol)**

Indicated for the management of reversible bronchospasm associated with obstructive airway diseases in patients who require more than a single bronchodilator.

**Berodual®, Duovent®, (fenoterol/ipratropium bromide)**

Indicated for the prevention and treatment of reversible bronchospasm associated with bronchial asthma and especially chronic bronchitis with or without emphysema.

**Devices/CFC Transition**

The Montreal Protocol and several supplementary legally binding international agreements lay down the gradual elimination of all production and use of ozone depleting substances, particularly chlorofluorocarbons (CFCs) which have been widely used as aerosol propellants. Of particular relevance to Boehringer Ingelheim is the switch from CFC-driven Metered Dose Inhalers to those propelled by the more environmentally-friendly hydrofluoroalkanes (HFAs).

Boehringer Ingelheim has already launched **HFA-products** for their established bronchodilators **Berotec®**, **Berodual®** and **Atrovent®** in many countries, and has also given a lot of attention to the development of an alternative inhaler device that is propellant-free.

The result is the new **Respimat® Soft Mist™ Inhaler**, a highly innovative approach to inhaler technology that is designed to meet patients' needs and is also environmentally friendly.

**Respimat**  To learn more about **Respimat® Soft Mist™ Inhaler** we invite you to visit the new global **Respimat® website**.

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